UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

The Cleveland Clinic Foundation, et. al,	)	**CASE NO. 1:15 CV 2331**
	)	
Plaintiffs,	)	**JUDGE PATRICIA A. GAUGHAN**
	)	
	)	
Vs.	)	
	)	
True Health Diagnostics LLC,	)	**Memorandum of Opinion and Order**
	)	
Defendant.	)	

INTRODUCTION

This matter is before the Court upon Plaintiff's [*sic*] Motion for Temporary Restraining Order and Preliminary Injunction (Doc. 7). Plaintiffs, The Cleveland Clinic Foundation ("CCF") and Cleveland HeartLab ("HeartLab") (CCF and Heartlab, sometimes, collectively "plaintiff") filed this lawsuit against defendant, True Health Diagnostics. This is a patent infringement case. For the reasons that follow, the motion is DENIED.

FACTS

1. The patents

In 2003, researchers at CCF developed a test that assesses a patient's risk for cardiovascular disease ("CVD"). The test, called Myeloperoxidase or "MPO" testing, analyzes inflammation of the blood vessels. MPO is an enzyme released by white blood cells when inflammation occurs in the body. (Penn Decl. at ¶ 18). When an artery wall is damaged or becomes inflamed, MPO is released into the blood stream in an effort to kill bacteria. (*Id.*). Thus, MPO is an early symptom of many types of CVD. (*Id.* ¶ 9).

CCF filed a series of patent applications relating to MPO. The Patent and Trademark Office ("PTO") granted CCF's applications, and it is currently the owner of the three patents at issue in this lawsuit: U.S. Patent No. 7,223,552 ("the '552 patent"); U.S. Patent No. 7,459,286 ("the '286 patent"); and U.S. Patent No. 8,349,581 ("the '581 patent"). The '552 patent, which issued on May 29, 2007, has since been the subject of validity challenges by competitors in two reexamination proceedings before the PTO. The '552 patent was confirmed valid in both proceedings, most recently in 2011.

The patents teach a method of analyzing MPO biomarkers in a patient's blood sample to predict a patient's potential for heart disease. They do so by comparing the level of MPO found in the patient's blood sample with levels of MPO in control subjects to see if the patient has elevated levels of MPO.

2. Plaintiff's development and commercialization of MPO testing

In 2009, CCF launched HeartLab to begin commercialization of MPO testing. HeartLab is the exclusive licensee of the '552, '286, and '581 patents. (*Id.* at 10). CCF and HeartLab have

invested millions of dollars in their effort to build the MPO testing market. (Orville Decl. ¶ 12). They are conducting ongoing medical and scientific studies, sought FDA approvals, and obtained Medicare reimbursement status for MPO testing. (*Id.* at ¶ 8). They have focused considerable effort on developing stringent manufacturing and quality standards and also invested in educational programs about MPO testing. (*Id.*; Penn Decl. ¶¶26, 29-38).

HeartLab both performs lab analysis of patients' blood samples at HeartLab and, when volume is large enough, it will manufacture MPO testing kits for sale to other labs. (Orville Decl. ¶ 11). CCF's and HeartLab's efforts to develop and commercialize MPO testing have been quite successful. At its inception, HeartLab had eight employees who performed only a few hundred MPO tests. (Orville Decl. ¶¶ 9, 13). It now has 140 employees who will perform hundreds of thousands of MPO tests in 2015. (Orville Decl. ¶¶ 9-10, 13).

3. The alleged infringing actions

Defendant, a lab services company that performs CVD testing, was formed in March 2014. In September of 2015, defendant purchased some of the assets of Health Diagnostics Lab ("HDL") in a bankruptcy proceeding. Prior to its bankruptcy, HDL had used HeartLab for its MPO testing through a Laboratory Services Agreement. In its bid for HDL's assets, defendant sought HDL's customer list, including HDL's MPO testing customers, but expressly excluded HDL's Laboratory Services Agreement with HeartLab.

Concerned that defendant might use the technology in the MPO patents without authorization, HeartLab's CEO emailed defendant on September 14, 2015, to advise defendant that use of the MPO testing procedures would infringe the patents at issue. Defendant did not respond to the email. After learning anecdotally that one of defendant's salespersons was

representing to former HDL customers that defendant was offering an MPO test from HeartLab and was HeartLab's exclusive partner, plaintiff began an investigation to determine if defendant was offering MPO testing.

In mid-October, HeartLab acquired one of defendant's lab tests which showed that defendant was conducting MPO tests. Shortly thereafter, HeartLab discovered more of defendant's lab reports with MPO testing results. The reports all use different ranges for establishing the risk of a CVD event, which HeartLab claims "indicates a lack of quality ...[and that defendant] is not adhering to standard laboratory regulations and procedures." (Pl.'s Br. at 15). According to HeartLab, defendant's lack of quality control standards is "putting the entire MPO market segment at risk." (*Id.*). Plaintiff also states that "because most of the MPO market views ... HeartLab as the sole source of MPO as well as the MPO innovator, any misstep by [defendant] will in all likelihood be blamed on ... HeartLab–especially in view of [defendant's] insinuation that it is a partner of ... HeartLab." (*Id.* at 18).

Thereafter, plaintiff filed this lawsuit alleging that defendant infringes the '552, '286, and '581 patents. It now moves for a temporary restraining order and preliminary injunction enjoining defendant from infringing the patents-in-suit. Defendant opposes plaintiff's motion.

ANALYSIS

Federal Rule of Civil Procedure 65 governs the issuance of temporary restraining orders and preliminary injunctions.

In order to obtain a preliminary injunction, a patentee must show: "(1) reasonable likelihood of success on the merits; (2) irreparable harm; (3) that the balance of hardships tips in its favor; and (4) the impact of the injunction on the public interest." *Jack Guttman, Inc. v.*

Kopykake Enters., 302 F.3d 1352, 1356 (Fed.Cir.2002). "The denial of a preliminary injunction pursuant to 35 U.S.C. § 283 is within a district court's discretion." *Novo Nordisk v. Sanofi-Aventis U.S. LLC*, 290 Fed. Appx. 334, 335 (Fed. Cir. 2008). The Federal Circuit will "reverse such a decision only when an appellant demonstrates that the factors relied on by the district court [were] clearly erroneous and that a denial of the preliminary relief sought would amount to an abuse of the court's discretion upon reversal of an erroneous finding. *Id*. (*citing New Eng. Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878, 882 (Fed.Cir.1992)(internal quotations omitted)).

DISCUSSION

1. Likelihood of success on the merits

Plaintiff argues that it demonstrates a likelihood of success on the merits as to both infringement and validity. According to plaintiff, the claim construction process is straightforward and requires the construction of only two claim terms. Plaintiff also argues that its patents are valid and have successfully gone through an extensive reexamination process. Defendant argues that plaintiff's patents are invalid because they are based on ineligible subject-matter. Defendant also disputes that plaintiff establishes a likelihood of success on the issue of infringement.

Because the Court finds that plaintiff fails to show a likelihood of success on the merits as to validity, the Court will address this issue first.

> The presumption of validity of a patent is a procedural device that places the burden of going forward and the ultimate burden of persuasion at trial on one attacking the validity of a patent. *See* 35 U.S.C. § 282 (1988); *Roper Corp. v. Litton Systems, Inc.*, 757 F.2d 1266, 1270 (Fed.Cir.1985). However, at the preliminary injunction stage, because of the extraordinary nature of the relief, the patentee carries the burden of showing likelihood of success on the merits with respect to the patent's validity, enforceability, and

infringement.

Nutrition 21 v. United States, 930 F.2d 867, 870 (Fed. Cir. 1991). Thus, the burden is on the plaintiff to make a "clear showing" that the patent is valid. *Id*.

Upon review, the Court finds that plaintiff fails to make a clear showing that the patents-in-suit are valid. Pursuant to 35 U.S.C. § 101, [w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore...." Section 101 is limited, however, and does not cover "laws of nature, natural phenomena, and abstract ideas." *Alice Corp. Pty. Ltd v. CLS Bank International*, 134 S.Ct. 2347, 2354 (2014). In "applying the § 101 exception, we must distinguish between patents that claim the 'building block[s]' of human ingenuity and those that integrate the building blocks into something more." *Id*. (*citing Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289, 1303 (2012)).

In *Alice*, the Supreme Court employed a two-part test "for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Id*. at 2355. Courts must tread carefully because "at some level, all inventions...embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Id*. at 2354. First, the court must determine "whether the claims at issue are directed at a patent-ineligible concept." If the claims are so directed, the Court must proceed to step two, which involves a determination as to whether the patent contains an "inventive concept," which is described as "an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself." *Id*. (Internal citations and quotations omitted).

In *Mayo*, the Supreme Court addressed the validity of a patent designed to "help doctors who use thiopurine drugs to treat patients with autoimmune diseases determine whether a given dosage level is too low or too high." 132 S.Ct. at 1294. Specifically, the patent described a process of evaluating the safety of the concentrations of a particular metabolite in a person's blood. The Federal Circuit determined that in addition to the natural correlations, the patent claimed specific steps of administering a thiopourine drug and determining the resulting metabolite level. As such, the Federal Circuit determined that the patent was directed at patent-eligible subject matter. The Supreme Court reversed, finding:

> To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.

Id. at 1298.

In a series of cases following *Mayo*, the Federal Circuit invalidated a number of patents directed at medical testing. *See, Ariosa Diagnostics, Inc. V. Sequenon, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015); *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation*, 774 F.3d 775 (Fed. Cir. 2014) (affirming denial of preliminary injunction based on patent-ineligible subject matter with respect to patents directed at methods to identify mutations in DNA sequences); *PerkinElmer, Inc. v. Intema Ltd.*, 496 Fed. Appx. 65 (Fed. Cir. 2012)(patent disclosing specific screening methods to estimate the risk of fetal Down syndrome held invalid).

Here, by plaintiff's own admission, its "MPO Patents analyze the myeloperoxidase biomarker." Although plaintiff argues that its patents contain an inventive concept because "measuring the MPO levels to determine the risk of having atherosclerotic cardiovascular disease is not known in the prior art," the Court is not convinced at this stage in the litigation that

this constitutes an inventive concept. Rather, it appears that the correlation between MPO levels and cardiovascular disease is more akin to a law of nature. And, as defendant correctly notes, although the "discovery" of a law of nature may be significant, the significance alone does not render the discovery patentable.

The Court is further not convinced that plaintiff has demonstrated that the patents-in-suit contain "an element or combination of elements" sufficient to satisfy step two of the *Mayo/Alice* test. Plaintiff simply argues that its patents require "measurement of a closed set of specific bodily samples" and, therefore, its patents apply a "phenomenon in a combination of steps that has never been done before." At this point in the litigation, the Court disagrees. Measuring a sample of blood or blood product[1] appears to be a "well-understood, routine and conventional activity" known in the scientific community.

For the first time in its reply brief, plaintiff appears to argue that the patents satisfy *Mayo/Alice* because they require the "unity of two crucial innovations." Namely, plaintiff claims that the patents measure MPO using certain "claimed" techniques and recognize that MPO can predict CVD risk. Plaintiff, however, wholly fails to point the Court to specific language contained in the patents that supports these propositions. Rather, plaintiff merely states that the claims are "drawn to a novel application and implementation of MPO testing," but fails to offer any explanation beyond this general statement. Plaintiff makes no other argument, nor does plaintiff point to any specific claim language in any of the patents-in-suit that supports a

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[1] Plaintiff does not point to any specific language in its patents in making this argument. The Court notes, however, that the bodily samples identified in the patents consist of "blood, serum, plasma, blood leukocytes selected from the group consisting of neutrophils and monocytes, or any combination thereof."

finding of validity.[2] As such, the Court finds that plaintiff fails to make a "clear showing" that its patent is valid in light of *Mayo.*

Having concluded that plaintiff fails to establish a likelihood of success on the merits with respect to validity, the Court need not address infringement.

2. Irreparable harm[3]

The Court further finds that plaintiff fails to demonstrate that it will suffer irreparable harm absent the issuance of a temporary restraining order or preliminary injunction. Plaintiff argues that it will suffer loss of goodwill and damages to its reputation. Plaintiff claims that a "single false result in one of defendant's dubious tests could tar the entire MPO market segment." Plaintiff also argues that defendant's tests are "substandard and inconsistent." The Court agrees with defendant, however, that plaintiff fails to produce any evidence supporting these assertions. Although plaintiff produces an affidavit supporting the proposition that defendant's tests are unreliable and will cause confusion, there is no evidence that any confusion or errors actually occurred. Plaintiff's evidence is speculative at best. *See, Bettcher Industries, Inc. v. Bunzl USA, Inc.*, 692 F.Supp.2d 805 (N.D. Ohio 2010); *Lopes v. International Rubber*

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[2] Although plaintiff repeatedly notes that the patents-in-suit were subject to extensive reexamination processes, those processes predated the Supreme Court's decision in *Mayo*.

[3] According to plaintiff, irreparable harm is presumed if plaintiff clearly establishes validity and infringement. The case plaintiff relies on, however, was abrogated and is no longer good law. See, *Robert Bosch, LLC v. Pylong Mfg. Co.*, 659 F.3d 1142 (Fed. Cir. 2011)(abrogating *Smith Int'l, Inc. v. Hughes Tool Corp.*, 718 F.2d 1573, 1581 (1983) in light of *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006)).

Distributors, Inc., 309 F.Supp.2d 972 (N.D. Ohio 2004). Moreover, in response to plaintiff's speculative evidence, defendant produced evidence indicating that it has *not* received any customer complaints regarding false positive or negative results or confusion about the values used in defendant's testing. *See*, Ward Decl. At ¶¶ 16-17; Grottenthaler Decl. At ¶ 18-19.

For these same reasons, the Court rejects plaintiff's argument that monetary harm is incalculable in this case because of the nature of the market. Plaintiff claims that the market for MPO testing is new and growing and that "it may not be able to keep financing its efforts to grow the market." Again, however, plaintiff offers no evidence in support of this assertion. To the contrary, plaintiff's own allegations and evidence show that plaintiff has significantly grown its company from an original eight employees to a current 140. Plaintiff also points out that it now sells "hundreds of thousands" of MPO tests. As such, the Court rejects defendant's argument that monetary harm is incalculable.

Plaintiff also argues that defendant usurped market share when it purchased the customer list from HDL. Plaintiff, however, fails to point to any evidence that it lost a single customer as a result of defendant's alleged infringement. Thus, plaintiff's reliance on *Trebro Mfg. v. FireFly Equip*., LLC, 748 F.3d 1159 (Fed. Cir. 2014) is misplaced.[4] In all, the Court finds that plaintiff fails to establish irreparable harm.

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[4] *Trebo* involved a unique market in which product sales were extremely limited. The Federal Circuit held that the district court erred in rejecting evidence showing "likely loss of market share and loss of access to customers." Here, by plaintiff's own admission, the market for MPO testing is much larger than the market for sod harvesters, the product at issue in *Trebo*. Moreover, plaintiff offers no evidence of lost market share or loss of access to customers.

3. Balance of hardships/public interest

Plaintiff argues that once a Court finds likelihood of success on the merits and irreparable harm, an injunction should be issued unless the balance of hardships weighs "decidedly" in favor of defendant. Here, however, the Court found neither likelihood of success on the merits nor irreparable harm. Thus, the Court finds that this factor does not weigh in favor of the issuance of a restraining order or injunction. For the same reasons, the public interest is not served by the issuance of a restraining order or injunction.

CONCLUSION

For the foregoing reasons, Plaintiff's [*sic*] Motion for Temporary Restraining Order and Preliminary Injunction is DENIED.

IT IS SO ORDERED.

/s/ Patricia A. Gaughan
PATRICIA A. GAUGHAN
United States District Judge

Dated: 11/18/15